



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

g1638d

60 8th Street, N.E.
Atlanta, Georgia 30309

August 1, 2001

VIA FEDERAL EXPRESS

Howard I. Halpern, CEO
Buckhead Beef
2194 Marietta Boulevard
Atlanta, GA 30318

Warning Letter
01-ATL-69

Dear Mr. Halpern:

On June 25 - 27, 2001, the Food and Drug Administration (FDA) conducted an inspection of your multiple food storage warehouse, located at Atlanta, Georgia. During that inspection, our investigators documented serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause the fresh histamine-forming fish (e.g. mahi mahi) stored at your facility to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviation of concern is as follows:

You must have and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for histamine-forming fish to control the food safety hazard of histamine formation.

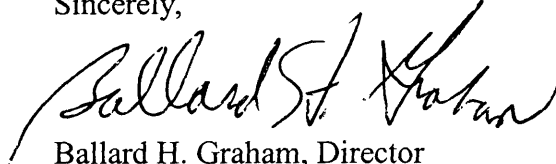
We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter and the FDA 483 issued to April Staebell, Director of Quality Assurance, at the end of the inspection may not list all the deviations at your facility. You are responsible for ensuring that your storage warehouse operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with a large initial "B" and a stylized "H".

Ballard H. Graham, Director
Atlanta District